

EXHIBIT B

1 believe that you cannot rely on the opinions of
2 the FDA?

3 MS. GEIST: Objection to form.

4 THE WITNESS: That's a loaded
5 question.

6 It depends. Sometimes I do. But I
7 can respectfully disagree when they're not the
8 ones using it and seeing it and treating patients
9 every day.

10 BY MS. LIUZZA:

11 Q. Okay. So you, as an expert in this
12 field, pick and choose which positions or
13 statements by the FDA you will or will not rely
14 on; is that correct?

15 MS. GEIST: Objection to form and
16 argumentative.

17 THE WITNESS: I don't have a choice
18 on what I can rely on.

19 (Court reporter clarification.)

20 MS. GEIST: And argumentative.

21 THE WITNESS: I don't have a choice
22 on what I can rely on. I can't use a product
23 that's not approved by the FDA or available. It
24 doesn't mean I agree with all of their
25 commenting.

1 BY MS. LIUZZA:

2 Q. Have there been other statements or
3 positions issued by the FDA with regard to
4 transvaginal mesh that you have disagreed with?

5 MS. GEIST: Objection to form.
6 Overly broad.

7 THE WITNESS: It's hard to answer
8 that. You would have to give me a specific.

9 BY MS. LIUZZA:

10 Q. Okay. But as we sit here today, we
11 know of one instance. You disagree with the news
12 release; is that correct?

13 A. I do.

14 Q. Okay. Any other positions or
15 statements that you disagree with the FDA that
16 you can recall as you sit here today?

17 MS. GEIST: Same objection. Overly
18 broad.

19 THE WITNESS: Not off the top of my
20 head.

21 BY MS. LIUZZA:

22 Q. Have you previously opined in any
23 studies or papers that the use of vaginal mesh
24 products for the treatment of pelvic organ
25 prolapse was safe and effective?

1 correct?

2 MS. GEIST: Objection to form.

3 THE WITNESS: Different as compared
4 to?

5 BY MS. LIUZZA:

6 Q. Likely, medical certainty.

7 A. Yes.

8 Q. So, again, here you're saying it's a
9 possibility that this is -- you're using that for
10 possibility; is that correct?

11 A. I cannot rule out the fact that she
12 had preoperative voiding dysfunction issues based
13 on her history.

14 Q. But you're not saying that to a
15 reasonable degree of medical certainty she had
16 those issues?

17 A. She definitely had those issues at
18 one point. We don't know if they resolved prior
19 to the sling, because there's no documentation to
20 support that.

21 Q. Have you ever treated a patient who
22 complained of pelvic pain -- pelvic pain
23 following implant of synthetic mesh in your
24 practice?

25 MS. GEIST: Objection to form.

1 define that.

2 BY MS. LIUZZA:

3 Q. Do you know the intensity of Ms.
4 Arruda's pain prior to her mesh implantation?

5 A. Only based on the records I have.
6 And there weren't a lot of -- there wasn't a lot
7 of mention specific to that, to be honest.

8 Q. Do you know the intensity of Ms.
9 Arruda's pain after her mesh implantation?

10 A. Again, based on only the records I
11 have.

12 Q. Did you rule out the Align T0 as a
13 cause of Ms. Arruda's pelvic pain in this case?

14 A. I did not rule it out.

15 Q. In your opinion, is the Align T0 a
16 possible cause of Ms. Arruda's pelvic pain in
17 this case?

18 A. I think it is a possible cause of
19 some of her pelvic pain, but not all.

20 Q. Do you believe that the Align T0 is
21 a probable cause of Ms. Arruda's pelvic pain in
22 this case?

23 MS. GEIST: Objection to form.

24 THE WITNESS: I can't say that,
25 because she has so many other reasons that I

1 factor of painful sex in a patient following
2 implantation?

3 MS. GEIST: Objection to form.
4 Overly broad.

5 THE WITNESS: Yes.

6 By MS. LIUZZA:

7 Q. Have you ever removed a synthetic
8 sling to alleviate a patient's painful sex?

9 MS. GEIST: Same objection. Overly
10 broad.

11 THE WITNESS: Rarely, but yes.

12 BY MS. LIUZZA:

13 Q. Can the Align TO sling cause painful
14 sex in a patient following implantation?

15 MS. GEIST: Objection to form.

16 THE WITNESS: It's possible.

17 BY MS. LIUZZA:

18 Q. Is it your understanding that one
19 reason for Ms. Arruda's mesh removal on February
20 18, 2012 was to alleviate painful sex that she
21 was experiencing?

22 A. Yes.

23 Q. Did you rule out the Align TO as a
24 cause of the painful sex that Ms. Arruda was
25 experiencing?

1 A. I did not rule it out completely;
2 no.

3 Q. And, again, you list several things
4 that you believe could possibly be the reason
5 that she was experiencing painful sex. Is that
6 correct?

7 MS. GEIST: Objection to form.

8 THE WITNESS: It could be the reason
9 or in addition to; yes.

10 BY MS. LIUZZA:

11 Q. And one of them, again, is a long
12 history of back pain. Is that correct?

13 A. Indirectly, yes.

14 Q. How did you determine that the long
15 history of back pain could not be ruled out as a
16 cause or contributing factor of Ms. Arruda's
17 painful sex?

18 A. Again, because of the pelvic floor
19 muscles that are part of that, as a reaction they
20 can tense up and cause pain during sex.

21 Q. Are you relying on anything in Ms.
22 Arruda's medical records that supports your
23 position that her long history of back pain could
24 be the cause of her painful sexual experience?

25 A. I'm giving possibilities based on

1 bowels and the things that occupy the pelvis or
2 the joints, or other musculature, they can have a
3 reaction of levator spasm, and that can cause
4 pain or dyspareunia in patients.

5 Q. How about for Crohn's disease?

6 A. Well, that's part of the bowel
7 complaints.

8 Q. So your opinions would be the same
9 as related to my questions about bowel issues?

10 A. Yes. I mean, the bowels extend
11 toward -- I mean, the bowels aren't just the
12 bowels. They're the rectum, as well, and the
13 rectum is just behind the vagina. So they're all
14 in the same location. Sometimes it can be very
15 difficult to determine where is the pain
16 originating.

17 Q. Are you relying on anything in Ms.
18 Arruda's medical issues other than the presence
19 of bowel issues and Crohn's disease that provides
20 a linkage of those two to Ms. Arruda's complaints
21 of painful sex?

22 A. No. But even her GYN, at times,
23 mentions bowels when he's talking about pain with
24 no other mention of any other etiology. So it
25 was clearly on his mind, as well.

1 Honestly, she has a poor exam and
2 evaluation of her pain in her records. I don't
3 think it was fully vetted.

4 Q. Okay. Have you ever treated a
5 patient who complains of more frequent UTIs
6 following implantation of synthetic mesh?

7 MS. GEIST: Objection to form.
8 Overly broad.

9 THE WITNESS: Occasionally.

10 BY MS. LIUZZA:

11 Q. Have you ever treated a patient who
12 complained of more frequent UTIs following
13 implantation of the Align TO mesh?

14 A. Specifically, no. I don't recall.

15 Q. Is it no, or you don't recall?

16 A. I don't recall.

17 I mean, the answer would be no based
18 on my memory, but it's hard to be specific to a
19 particular sling.

20 Q. Have you ever determined that a
21 synthetic mesh sling was the cause or
22 contributing factor of urinary tract infections
23 following implantation?

24 MS. GEIST: Objection to form.
25 Overly broad.

1 MS. GEIST: Objection to form.

2 Overly broad. Calls for speculation.

3 THE WITNESS: Any incontinence
4 procedure, including slings, not specifically
5 Align, can increase in some patients a risk of
6 urgency and frequency postoperatively.

7 BY MS. LIUZZA:

8 Q. So the implantation of the Align TO
9 sling can lead to urge incontinence in a patient;
10 correct?

11 MS. GEIST: Same objection. Overly
12 broad.

13 THE WITNESS: I wouldn't say
14 specifically urge incontinence, but it can
15 increase urgency.

16 BY MS. LIUZZA:

17 Q. Did you rule out Ms. Arruda's
18 continued urge incontinence as being caused by
19 the Align -- implantation of the Align TO sling?

20 A. I did not rule it out.

21 Q. Why not?

22 A. Because, as we just mentioned, it is
23 a possible risk factor for increasing those
24 symptoms in some patients.

25 Q. Are there any documents or records